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A Multicenter, Prospective, Randomized, Contralateral Study of Tissue Liquefaction Liposuction vs Suction-Assisted Liposuction

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Abstract

Background: Tissue liquefaction liposuction (TLL) deploys a novel energy source utilizing a stream of warmed, low-pressurized, and pulsed saline to extract fat tissue.

Objectives: Compare TLL to suction-assisted liposuction (SAL) to determine which device is more efficient for surgeons and provides better recovery for patients.

Methods: Thirty-one adult female patients were followed prospectively in a contralateral study design comparing differences in bruising, swelling, tenderness, and incision appearance ratings between TLL and SAL procedures. Surgical efficiency and appearance of the lipoaspirate were also compared.

Results: All 31 patients successfully completed the study. For TLL and SAL procedures, the average volumes of infusion (1.242 vs 1.276 L) and aspirated supernatant fat (704 vs 649 mL) were statistically similar. TLL median fat extraction rate was faster than SAL (35.6 vs 25 mL/min; $P < 0.0001$), and stroke rate was reduced in TLL vs SAL procedures (48 vs 120 strokes/min; $P < 0.0001$), and both were statistically significant. The mean total scores for bruising, swelling, treatment site tenderness, and incision appearance were lower, indicating improved patient recovery on the TLL side.

Conclusions: TLL and SAL techniques produced comparable volume of fat aspirate. TLL demonstrated a 42% faster fat extraction rate and a 68% reduction in arm movements needed to complete the procedure compared to SAL, both of these differences are statistically significant. The TLL side was noted to have reduced bruising and swelling and improved incision site appearance with less tenderness compared to the SAL side.

Level of Evidence: 2

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Liposuction is the most popular cosmetic surgery and accounted for over 400,000 US procedures in 2016.[1] Since the introduction of tumescent liposuction in the mid-1980s,[2-4] there have been many technological innovations, but in a 2011 survey of 492 US plastic surgeons, suction-assisted liposuction (SAL) was noted to be the preferred method of fat removal among respondents.[5]

This randomized, single-blind, contralateral study examined a novel liposuction method: tissue liquefaction liposuction (TLL) (HydraSolve, Andrew Technologies,

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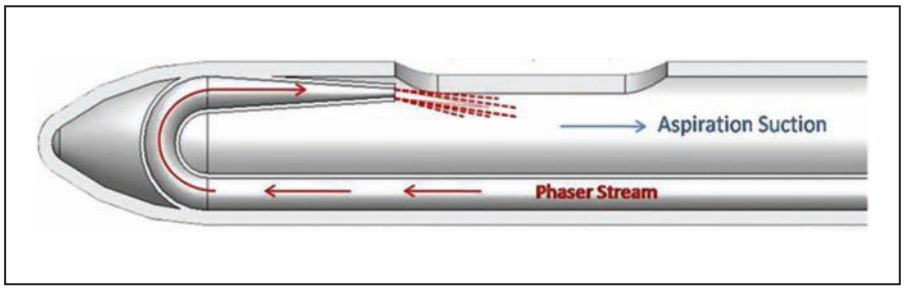

Figure 1. Tissue liquefaction liposuction (TLL) cannula schematic (reprinted with permission from Andrew Technologies).

Tustin, CA). In TLL a stream of warmed (37-55°C), low-pressurized (300-1100 psi), and pulsed saline is deployed inside the cannula (Figure 1). (The saline is *not* medicated, and it does *not* exit the cannula into the tissue bed.) Subcutaneous tissues are drawn into the interior of the cannula by suction where the saline stream impacts these tissues and selectively liquefies fat while not liquefying blood vessels, nerves, and connective tissue. Liquefaction of fat tissue in TLL is a process of cell disaggregation, not of emulsification; fat tissue cells are separated into a multicell suspension composed of small cell clusters that are approximately 500 to 2000 μm in diameter.[6] It is believed that cell disaggregation occurs because of deactivation of adhesive glycoproteins that are located on the surface of fat cell membranes. The TLL lipoaspirate contains more saline than the SAL lipoaspirate; with gravity separation the fat tissue rises to the top of the collection container and that layer is considered the volume of aspirated fat tissue, while the saline layer below is not counted as aspirated fat tissue. The quality of TLL harvested fat for autologous fat transfer has been demonstrated in several studies,[6-11] and the device was also FDA 510(k) cleared[12] for Autologous Fat Transfer in 2013.

The purpose of this study was to compare the efficiency of fat extraction and the impact on patient recovery of the tissue-selective extraction of fat in TLL vs SAL procedures. Participants in the study were randomized to receive TLL on one side of the body and standard SAL at corresponding treatment sites on the other side of the body, with similar extraction volumes in each procedure. The contralateral study design allowed patients to act as their own controls, thereby reducing or eliminating interpatient variability. The fat extraction time, surgeons' exertion, and overall surgeon satisfaction were recorded at the time of the procedure. Bruising, swelling, treatment site tenderness, and incision appearance were followed for 30 days after treatment.

METHODS

This prospective study followed 31 female patients between January and September 2016 who underwent liposuction with TLL on one side of the body and SAL on the corresponding contralateral treatment site or sites. All patients were enrolled and treated by 5 plastic surgeons at 3 practices, with each surgeon treating at least 4 patients. All surgeons were provided with a study check list (Appendix A, available online as Supplementary Material at www.aestheticsurgeryjournal.com). Investigators performed the procedures and conducted postoperative patient assessments in a nonblinded manner. Patients were required to sign an informed consent document, and the study was conducted in accordance with protocols approved by the Western Institutional Review Board.

To be considered for enrollment, body mass index (BMI) between 19 and 30 kg/m^2 and suitable fat deposits were required. Enrollment required a negative urine pregnancy test and patients were instructed to discontinue use of birth control pills, nonsteroidal anti-inflammatory drugs, and any blood thinners for 3 weeks prior and 2 weeks after surgery. Additionally, patients consented to be followed for 30 days following surgery.

Patients were excluded from the study for: prior liposuction or surgery in the surgical area, redundant or inelastic skin, diabetes mellitus or cardiovascular disease, coagulation disorder or history of excessive bleeding, a history of or current narcotic use, a diagnosis of fibromyalgia, American Society of Anesthesiologists level 3 or higher, body dysmorphic syndrome, or a large tattoo that could obscure the presence or absence of bruising.

Liposuction surgery was performed on each side of the patient's body, with any of the following anatomic sites eligible: abdomen (lower or upper); thighs (medial, anterior, or lateral); or the waist, flanks, or hips. Prior to surgery, a coin flip was used to determine which technique was used first (TLL, heads; SAL, tails), and the left side was always treated first. All surgeries were performed under general anesthesia using "superwet technique."[13]

Prior to the first side being operated, an incision was made and a solution containing 0.25% bupivacaine with 1:200,000 epinephrine was injected using a 27-gauge needle. Standard tumescent infusion solution containing epinephrine (final dilution of 1:1,000,000) was infused at a volume approximately equal to the volume of fat to be removed.

Surgeons were instructed to wait 12 minutes before performing treatment with the first device. After the conclusion of the left treatment side, injection of tumescent solution, followed by a 12-minute wait time, was repeated before treating the right side with the other device.

For the TLL portion of the procedure, a 22.0-cm long cannula (HydraSolve; Tustin, CA) with a 3.0-mm outer diameter and two apertures was used. Per protocol, TLL was performed using phaser stream settings of 1100 psi and 46°C. For the SAL side, a Mentor (Byron, Irvine, CA) 3.0-mm outer diameter, three aperture, 26.0-cm Mercedes cannula (Mentor Catalog # MER326S) was used. Extracted lipoaspirate from each device was collected in separate waste canisters, which were allowed to gravity separate for two hours before measuring the amount of settled supernatant fat.

Measurements and Outcomes

All surgical outcomes were recorded using a "SURGEON REPORT FORM" and recovery assessments were recorded using an "INVESTIGATOR ASSESSMENT FORM" (Appendices B-C, available online as Supplementary Material at www.aestheticsurgeryjournal.com). For each device, total fat extraction time was recorded using a stopwatch. Stroke rate for each device was recorded by averaging the number of strokes performed in a 10-second period in two separate intervals. (An OR technician announced the start of a 10 second interval on a stopwatch while the surgeon counted out loud the number of strokes.) Patients were required to return for follow-up visits on postoperative day 1 and again on postoperative days 4 to 6; 8 to 10; and 29 to 31. At each clinical visit, the incision and treatment sites were observed and photographed. The treatments were complimentary for enrolled patients, and they were compensated for showing up for their follow-up visits, to assure compliance in completing the study.

Statistical Methods

The primary endpoint was the total score of bruising, swelling, tenderness, and incision appearance ratings recorded on the INVESTIGATOR ASSESSMENT FORM. The repeated measures of total scores at visits 1, 2, and 3 for each treatment side were analyzed in a linear mixed effects model incorporating the random effects of patient and visit; and fixed effects of surgeon, visit, and treatment side. The interactions between visit and treatment side and between surgeon and treatment side were also considered. The normal distribution assumption necessary for validity of the linear mixed effects model was appropriate for the total scores.

For the majority of endpoints from the SURGEON REPORT FORM (lipoaspirate appearance, supernatant appearance, physical exertion, overall surgeon satisfaction, and lipoaspirate flow dynamics), the assumption of normal distribution was not appropriate for the ordinal ratings between 1 and 10 or their differences between TLL and SAL side. Therefore, the difference between TLL and SAL side was analyzed using the nonparametric (not requiring the normal distribution assumption) Wilcoxon signed rank test and by computing the 95% confidence intervals for the median paired differences.

In secondary analysis, fat extraction rates for both treatment sides were analyzed in a linear mixed effects model incorporating the random effects of patient and fixed effects of surgeon, treatment side, and interaction between surgeon and treatment side. The normal distribution assumptions necessary for validity of the linear mixed effects model were appropriate.

Using the conservative Bonferroni adjustment for multiple testing, we concluded that the difference between SAL and TLL side was significant if the P value for the test of the treatment difference was less than alpha = 0.05/14 = 0.00357. This allowed controlling for the family wise type I error at 0.05 level.

RESULTS

All of the 31 patients successfully completed the study and no complications were reported. All 31 patients in the study were available for analysis at all time points with one exception: one patient missed her last follow up visit (day 29-31), she was present for the first three postoperative visits (postoperative day 1, days 4-6, and days 8-10). All patients were female with an average age of 38.5 years (range, 26-54 years). Average height was 165.68 cm (range, 152.4-180.34 cm) and average weight was 68.93 kg (range, 51.71-92.53 kg) with a mean BMI of 25.1 kg/m^2 (range, 21.3-29.8 kg/m^2). Each patient was seen 4 times posttreatment to assess results, with the one exception already mentioned, where one patient missed the last visit at 29 to 31 days postoperative. Visit 1 occurred at posttreatment day 1 for all patients. Visit 2 averaged 5.3 days posttreatment (range, 4-7 days). Visit 3 averaged 8.3 days posttreatment (range, 8-10 days). Visit 4 averaged 29.5 days posttreatment (range, 29-32 days). The average volume of tumescent infusion fluid used in SAL procedures was 1.276 L (range 250-3100 mL) and the average volume of aspirated fat was 649 mL (range 200-1100 mL). The average volume of tumescent infusion fluid used in TLL procedures was 1.242 L (range 250-3100 mL) and the average volume of aspirated fat was 704 mL (300-1100 mL).

Investigator Assessment Form

When averaged across the surgeons, the mean total scores for bruising, swelling, treatment site tenderness, and incision appearance were lower (indicating more favorable scores) on the TLL side by 2.09 (95% CI: 1.04,

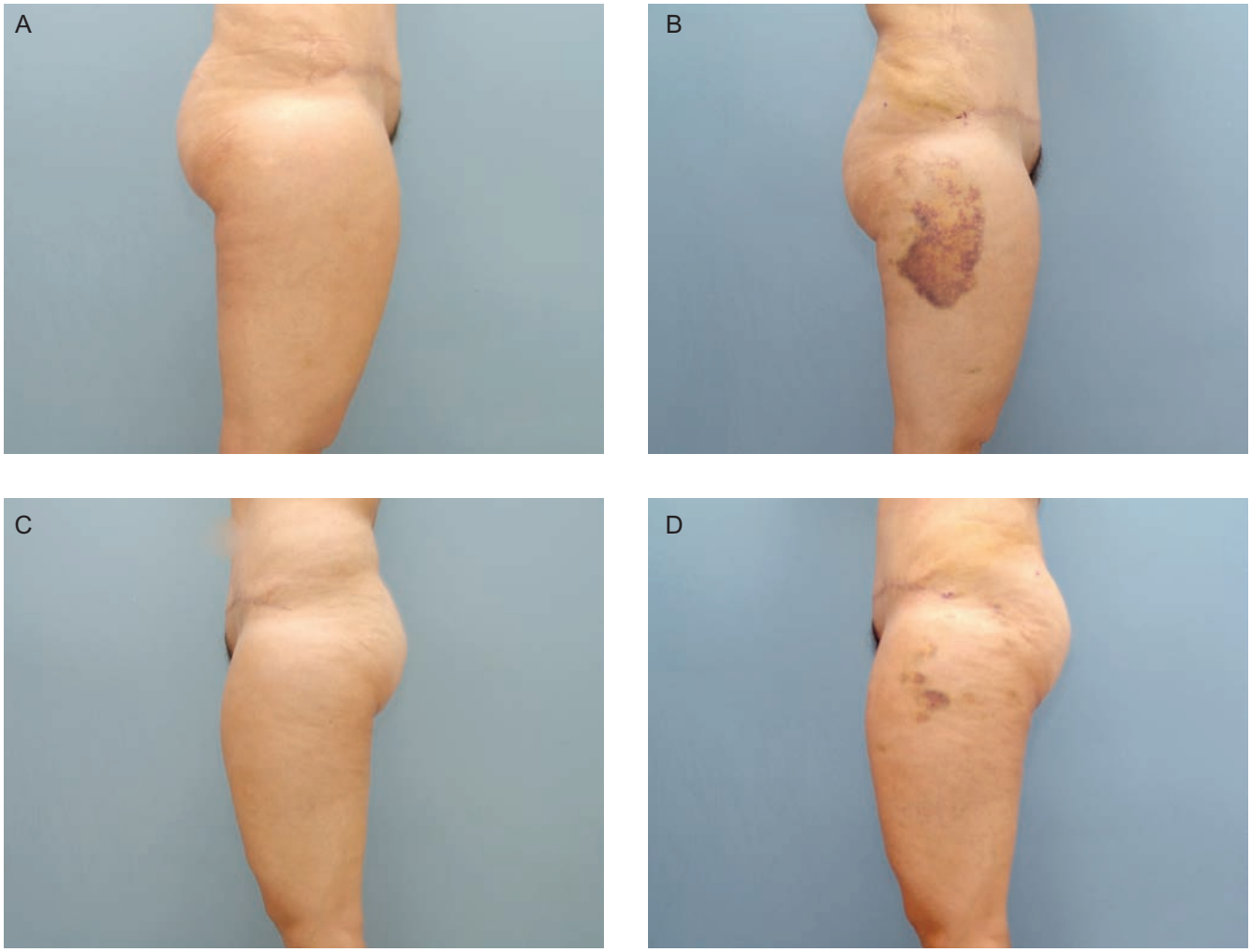

Figure 2. (A, C) Preoperative photographs of a 36-year-old woman. (B) Suction-assisted liposuction (SAL)-treated right side on day 7 and (D) Tissue liquefaction liposuction (TLL)-treated left side on day 7.

2.97, $P < 0.0001$) and the difference was statistically significant. This difference corresponded to a 16% lower mean total score for the TLL side (11.4; 95% CI: 10.7, 12.2) compared to the SAL side (13.1; 95% CI: 12.4, 13.9) (Figures 2-5).

Surgical Efficiency

The median fat extraction rate was 35.6 cc/min in TLL procedures vs 25 cc/min in SAL procedures ($P < 0.0001$), resulting in a 42% ($P < 0.0001$) faster fat extraction rate in the TLL side. Stroke rate was lower in the TLL vs SAL sides. The median stroke rate during TLL procedures was 48 strokes per minute compared to 120 strokes per minute with SAL ($P < 0.0001$), representing a 68% reduction in the number of arm movements by the surgeon when using TLL compared to SAL. Physical exertion as measured by surgeon survey was significantly better in TLL procedures (median score of 3 out of 10, with lower score indicating less perceived exertion) as compared to SAL procedures (median score of 8 out of 10; $P < 0.0001$).

Lipoaspirate Appearance

Appearance of the lipoaspirate and supernatant, as well as overall satisfaction with the quality of the extracted fat and lipoaspirate flow dynamics, were judged by the participating surgeons to be superior with TLL compared to SAL procedures (Figures 6 and 7). On a 10-point scale, with higher values indicating less satisfaction, median scores for lipoaspirate and supernatant appearance were 2 and 2, respectively, for TLL, compared to 7 and 8, respectively, for SAL ($P < 0.0001$). Likewise, the median score for lipoaspirate flow dynamics was 1 in the TLL group compared to 8 in the SAL group ($P < 0.0001$). On a 10-point scale, with higher values indicating more satisfaction, surgeons

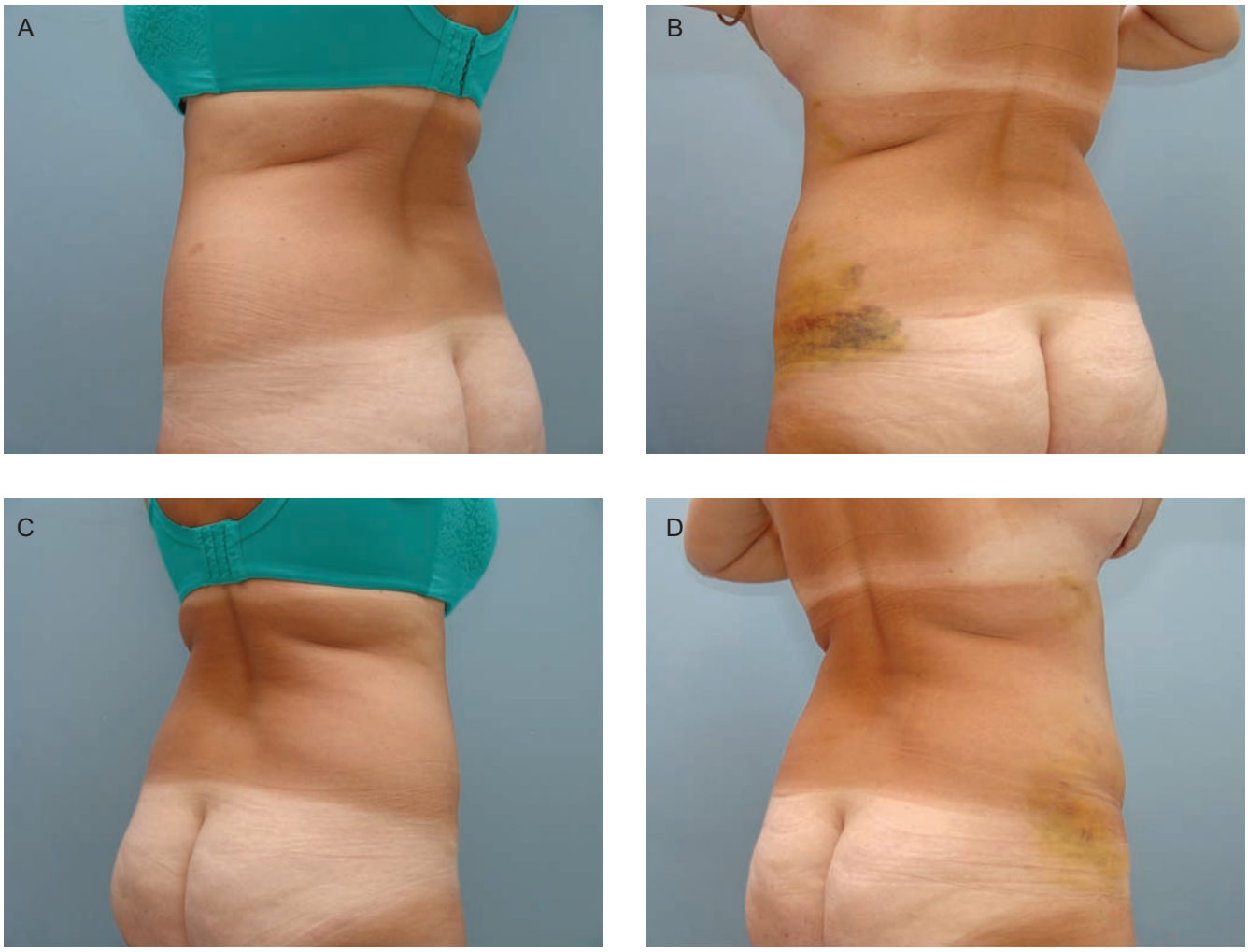

Figure 3. (A, C) Preoperative photographs of a 44-year-old woman. (B) Suction-assisted liposuction (SAL)-treated left side on day 4 and (D) Tissue liquefaction liposuction (TLL)-treated right side on day 4.

indicated greater satisfaction (median score of 9) with TLL compared to SAL (median score of 6; $P < 0.0001$).

DISCUSSION

The objective of this study was to demonstrate differences in surgical efficiency for surgeons and in post-treatment recovery for patients; this is the first study to show superiority across several clinical parameters for a new aesthetic body contouring device compared to standard suction-assisted lipoplasty (Table 1). This study was not designed (powered and long enough follow-up period) to evaluate the aesthetic outcome of these two devices; however, that was not the purpose of this study. The purpose of the study was to compare the procedural efficiency of TLL for surgeons and the recovery experience for patients to standard suction-assisted lipoplasty.

The physical impact of the selected treatment device on various tissues in the subcutaneous space during fat extraction may have important implications for patient recovery, as this may correlate with the degree of iatrogenic trauma. One interpretation of the results of this study is that because TLL's mechanism of fat tissue removal is more target tissue specific compared to SAL it is therefore likely to reduce collateral, nonfat tissue damage. Furthermore, the lower stroke rate in TLL procedures and slower surgeon movements also likely contributed to less potential for trauma at the surgical site, both inside the subcutaneous space and at the incision site. The fewer arm movements required by the surgeons to extract fat also represented a reduction in the level of physical exertion, with potential to lessen the risk of repetitive stress on surgeons' joints.

Prior to the introduction of blunt tip cannulae, lipoplasty procedures were often performed using sharp

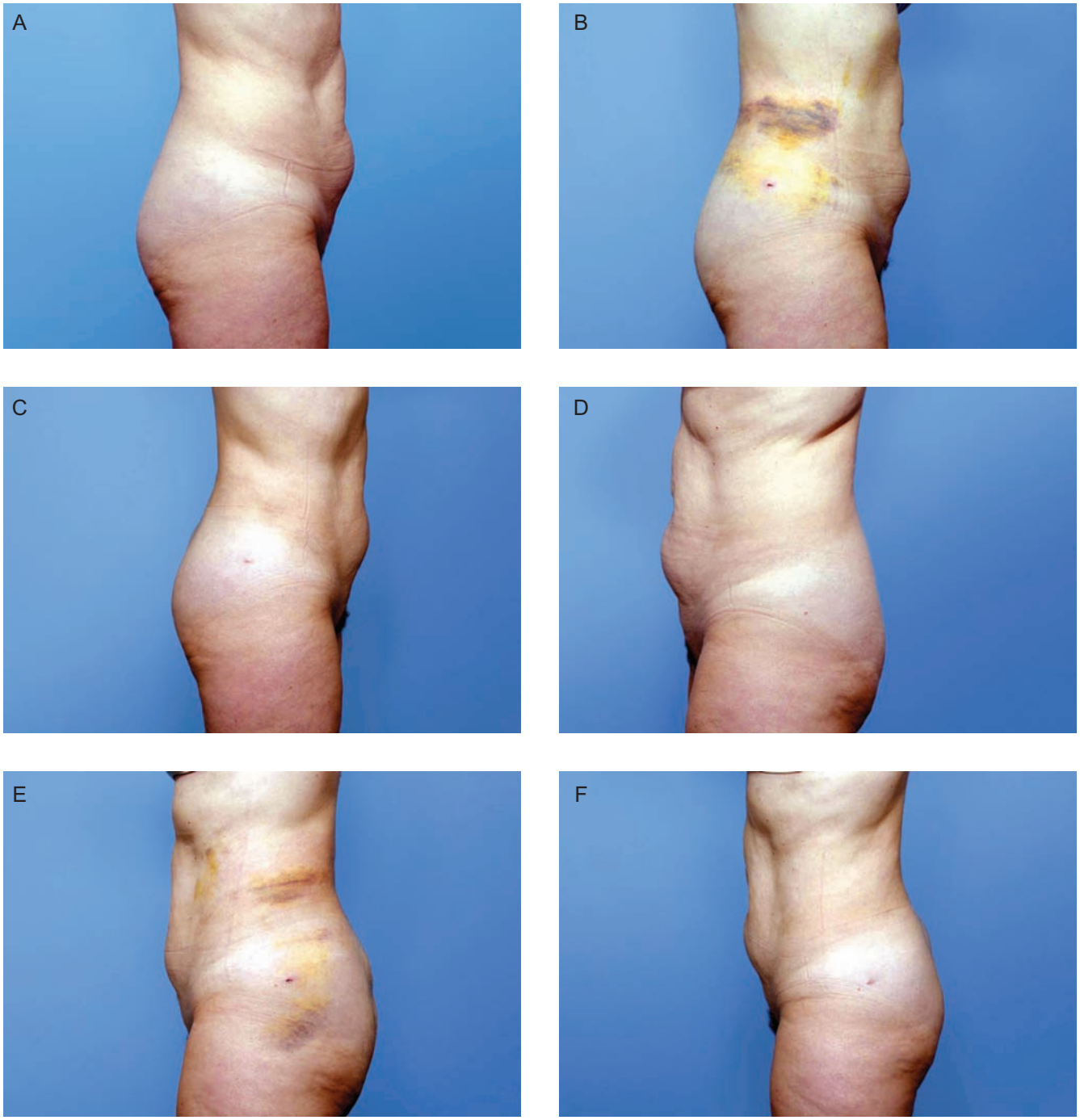

Figure 4. (A, D, G, J) Preoperative photographs of a 54-year-old woman. Suction-assisted liposuction (SAL)-treated right side on days 8 (B, H) and 30 (C, I). Tissue liquefaction liposuction (TLL)-treated left side on days 8 (E, K) and 30 (F, L).

curettage with large sections of fat and surrounding tissue mechanically sheared and suctioned from the surgical site.[14] However, these procedures were associated with significant morbidity, not insignificant rates of mortality, and, especially when dry techniques were employed, a high degree of blood loss.[14-20] Although tumescent and superwet techniques are associated with easier removal of fat cells, they do not address the need for a more target tissue specific mechanism of action of extracting fat tissue in liposuction which would reduce iatrogenic trauma to nonfat tissue.

The target tissue specific liquefaction of fat by TLL is made possible by using a novel energy source for surgery referred to as tissue liquefaction technology.

Figure 4. Continued

Originally invented for use in cataract extraction,[21] tissue liquefaction technology describes the use of a warmed, low-pressurized, and pulsed saline stream to liquefy target surgical tissue leaving nontarget tissue unchanged. In TLL, subcutaneous fat tissue is drawn inside the cannula where fat cells are disaggregated by the energized saline stream, which results in fat being separated into numerous smaller cell clusters. Blood vessels, nerve fibers, and connective tissue are not liquefied in this process and they remain in the subcutaneous space in a solid state of matter.[6] This mechanism significantly minimizes the physical exertion necessary to remove fat. As suggested by the results of the current study, this less traumatic fat removal may have significant benefits for healing, manifested in reduced bruising, swelling, and treatment site tenderness.

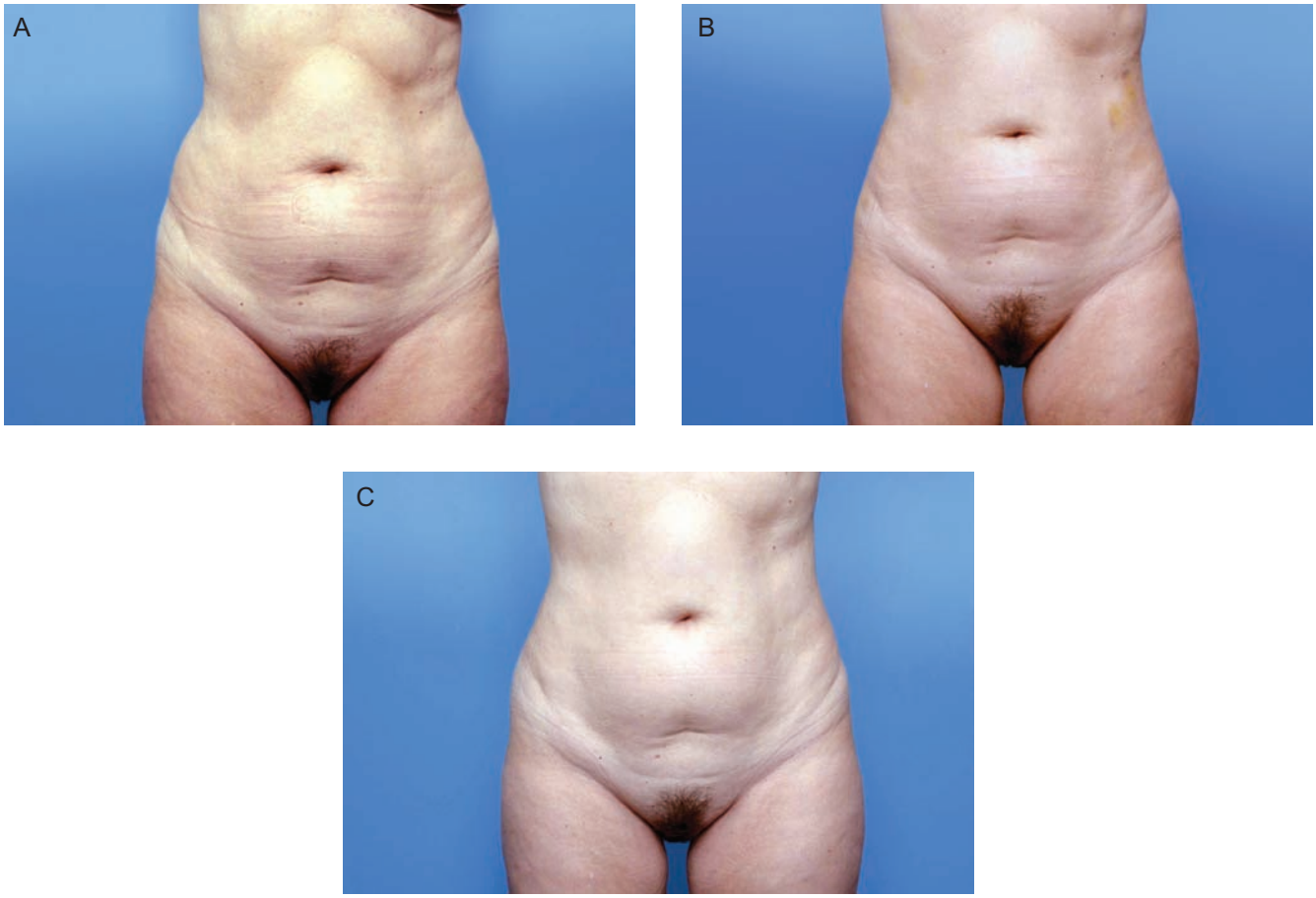

Figure 5. (A) Preoperative photograph of a 54-year-old woman (the same patient as in Figure 4). Her right side was treated with Suction-assisted liposuction (SAL) and her left side was treated with Tissue liquefaction liposuction (TLL). (B) Postoperative photograph at day 8. (C) Postoperative photograph at day 30.

Table 1. Results for the Primary Endpoints from the SURGEON REPORT FORM

Endpoint	TLL side (median)	SAL side (median)	Difference SAL vs TLL (95% CI)[a]	% Difference[b,c]
No. of strokes/min	48	120	−81.0 (−72.0 to −99.0)	68% ($P < 0.0001$)
Total no. of strokes	838	3078	+1909 (+1689 to +2752)	62% ($P < 0.0001$)
No. of arm movements/min	96	240	+162 (+144 to +198)	68% ($P < 0.0001$)
Fat extraction rate (cc/min)	35.6	25.0	+10.6	42% ($P < 0.0001$)

SAL, suction-assisted liposuction; TLL, tissue liquefaction. [a] confidence intervals for the median differences [b] % difference between HS and SAL as compared to SAL. If negative: % decrease in HS as compared to SAL; If positive: % increase in HS as compared to SAL. [c] All reported *P*-values are less than alpha (Type I error) of 0.00417 as required for significance using the Bonferroni correction for multiple testing

In the study population, ecchymosis was significantly reduced in the TLL group; however, the propensity to develop noticeable skin contusions was highly variable. Some degree of ecchymosis would be expected following any lipoplasty due to the invasive nature of the procedure. Yet, in the present study, there was significant interpatient variability in the extent of and propensity to develop ecchymosis. Because patients served as their own controls, any potential for known or unknown factors to confound the results is greatly diminished, especially as the potential for bruising would likely be equal on each side of the body.

Although SAL is still widely used in lipoplasty procedures, many surgeons have adopted other mechanisms for subcutaneous fat extraction. Future studies with TLL should examine potential differences in outcomes relative to other technologies. For purposes of the current study, using SAL as a comparator is reasonable, as it may well represent the current standard of care in lipoplasty procedures.

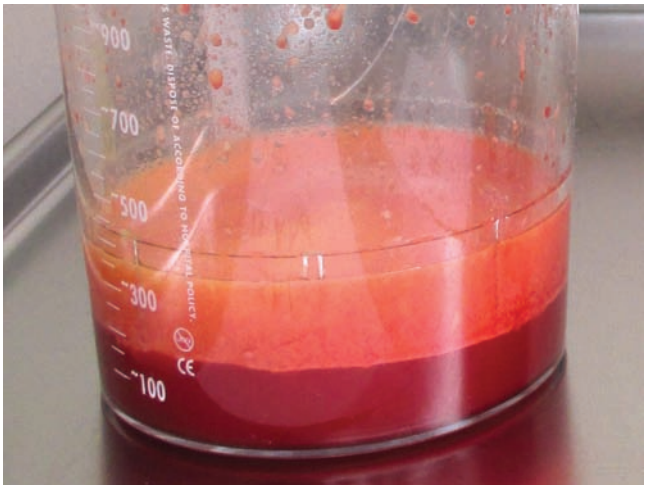

Figure 6. Suction-assisted liposuction (SAL) abdomen settled fat in waste canister.

Figure 7. Tissue liquefaction liposuction (TLL) abdomen settled fat in waste canister.

Subanalysis of surgical times from individual surgeons suggested a trend toward shorter extraction time using TLL in late vs early cases (data not shown). This is suggestive of a learning curve that may confound the results of the study. As well, the study enrolled relatively small numbers of patients and the duration of the study was short.

Nevertheless, for the purposes of studying postoperative healing and surgical efficiency of two technologies, both the number of patients and length of follow up were entirely appropriate.

The single blind nature of the study introduces the potential for confirmational bias. However, patients who participated in this study enrolled with the expectation for a quality aesthetic outcome on each side of the body, and participating surgeons were highly motivated to deliver on that promise, which reduces the potential for investigator bias.

A limitation of the study was the usage of a coin flip for randomization; a random number generator or randomization software perhaps could have been a better choice to guide randomization in the study.

The contralateral, multicenter, and multiple surgeon study design also helps to address potential for investigator bias. While surgical technique is a critically important element in final outcome, results from individual surgeons tended to cluster around the median finding, with few if any substantial outliers. The suggested uniformity in the results with TLL and SAL irrespective of the operator lends credibility to the findings and discounts the prospect of preconceived notions affecting results.

We have observed many plastic surgeons performing SAL and TLL. How fast they move the cannulae in these two types of body contouring methodologies is a function of the mechanism of fat removal: in SAL, it is cutting and shearing of tissue, in TLL it is the target tissue specific liquefaction of fat tissue. The typical stroke rate of a surgeon doing SAL is about 2.5 strokes every 1 second. The recommended stroke rate for TLL is: 1 stroke every 1.5 to 2 seconds as TLL removes fat most efficiently with that stroke rate. In a 10 second interval, the SAL stroke rate will usually be somewhere between 18 and 30, and the TLL stroke rate will be between 4 and 8 in a 10 second interval. We have observed that all you need is a 10 second interval to document this, because the stroke rates are consistent throughout the vast majority of the procedure, for both SAL and TLL.

Comparison of the quality of the aspirate was not the primary purpose of the study, so that is the main reason a more rigorous scientific methodology was not employed to characterize the blood content of the lipoaspirates. Early in the study design, the company did consult a Ph.D. cell biologist to help us determine if we could reliably perform a quantitative analysis of the hematocrit and hemoglobin levels in the lipoaspirates.

We took fresh TLL and SAL lipoaspirates and analyzed them in a Beckman Coulter Counter (Beckman Coulter, Inc., Life Science Division Headquarters, Indianapolis, USA). We found that this method was not scientifically valid. We came to the conclusion that to obtain scientifically accurate blood content measurements of lipoaspirates that we would have to develop a new protocol ourselves. Since the main purpose of the study was not about lipoaspirate quality, nor about the blood content of lipoaspirates, we decided to develop that methodology at a later date for a later study.

In this study, a superwet technique using a solution of bupivacaine with epinephrine was used based on the preference of one of the surgeons in the study, and all the other study surgeons agreed with it. It was not done to

minimize blood in the lipoaspirate. There was no waiting after this step was done, before the tumescent infusion was started.

CONCLUSION

This study demonstrated that TLL and SAL were each equally viable for moderate volume fat removal during liposuction procedures, while the former demonstrated a 42% faster fat extraction rate and a 68% reduction in arm movements needed to complete the procedure. The TLL side was noted in the first three postoperative visits to have reduced bruising, swelling, treatment site tenderness, and a better incision site appearance compared to the SAL side. Future studies should seek to enroll larger numbers of patients and should consider cases involving higher volume aspiration and/or body sites with traditionally more fibrous tissue depositions. Longer-term studies would be necessary to understand the implications of the current study in the context of final outcomes and overall aesthetic contour at the operative sites.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Disclosures

Dr Andrew is the Founder and Chief Scientific Officer of Andrew Technologies, is a co-inventor of Tissue Liquefaction Technology and HydraSolve®, and owns Andrew Technologies stock. Dr Godek is a co-inventor of HydraSolve® and owns Andrew Technologies stock. The other authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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